SEP 2 7 2000

K001986

ellman Surgitron IEC II

510 (k) Summary of Safety and Effectiveness

1. Submitter name and address:

Frank Lin, Ph.D.
Director of R&D engineering
ellman international
1135 Railroad Avenue
Hewlett, New York 11557

2. Device name and classification:

2.1 Device Name: Surgitron IEC II (Also known as Dual Frequency Surgitron)
2.2 Classification: Class 2 device, 21 CFR 878.4400
2.3 Common/Usual Name: RF Electrosurgical Generator

3. Date Prepared: September 14, 2000

4. Description of the device:

The ellman Surgitron IEC II enhanced capability Electrosurgery Generator described herein is a compact source of high power RF energy to be employed for a variety of radiosurgery procedures. This action is achieved by front panel selection of waveforms and power level. All selection is effected through push buttons and lamps which give the operator feedback of status. Power level for each mode is indicated by front panel digital displays which also show the status of self-test and monitoring. This display is interlocked with the controls to prevent operation when FAIL is displayed. The final output power control is made through foot and/or hand switches. Both Monopolar and Bipolar electrodes are provided. It is designed to comply with international safety standards.

5. The intended use/indication for use of the device:

For use by qualified surgeons for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurosurgical procedures.

6. Identification to predicate devices

* The BOVIE specialist electrosurgical Unit as a preamendments device marketed before May 28, 1976.
* ArthroCare System 2000 Electrosurgical Device For Neurology Application with K001588

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2000

Frank Lin, Ph.D.
Director of Engineering
Research and Development Department
Ellman International, Inc.
1135 Railroad Avenue
Hewlett, New York 11557

Re: K001986
Trade Name: Surgitron IEC II
Regulatory Class: II
Product Code: GEI
Dated: June 28, 2000
Received: June 29, 2000

Dear Dr. Lin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): k001986

Device Name: SURGITRON IEC II

Indication For Use:

For use by qualified surgeons for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurosurgical procedures.

for Mark N Melkerson
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001986

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The- Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)